K071681

Summary of Safety and Effectiveness for

Cytomics FC 500 MPL Flow Cytometer

1.0 General Information

Device Generic Name(s):	Automated differential cell counter
Device Trade Name(s):	Cytomics FC 500 MPL Flow Cytometer
Device Classification:	Class II medical device.
Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	June 18, 2007

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2.0 Legally Marketed Device(s)

The FC 500 MPL Flow Cytometer claims substantial equivalence to the previously cleared FC 500 Flow Cytometer.

FDA 510(k) Number(s): K030828

3.0 Device Description

The Cytomics FC 500 MPL Flow Cytometer (FC 500 MPL) is a bench top laboratory instrument designed for In Vitro Diagnostic Use in clinical laboratories.

The FC 500 MPL provides qualitative and quantitative measurement of biological and physical properties of cells and other particles. These properties are measured when the cells pass through one or two laser beams in single file.

4.0 Principle of Method:

The FC 500 MPL uses flow cytometric principles to determine qualitative and quantitative measurements of biological and physical properties of cells and other particles. These properties are measured when the cells pass through one or two laser beams in single file. The instrument can simultaneously measure forward scatter, side scatter, and five fluorescent dyes using one or two lasers at 488 nm and either 635 nm (solid-state laser) or 633 nm (HeNe laser). Therefore, the instrument can perform correlated multiparameter analyses of individual cells.

To ensure that the cells move through the laser beam one at a time, the instrument uses hydrodynamic focusing in the flow cell. As the stream of sheath fluid is flowing through the flow cell, a stream of sample is injected into the middle of the sheath stream. The sheath stream surrounds, but does not mix with the sample stream, and its pressure focuses the sample stream so that the cells flow through the laser beam single file.

Before the laser beam reaches the sample stream, cross-cylindrical lenses focus the beam keeping it perpendicular to the sample stream flow while making the beam small enough to illuminate only one cell at a time.

As the cells in the sample stream go through the sensing area of the flow cell, the laser beam illuminates them. The cells scatter the laser light and emit fluorescent light from fluorescent dyes attached to them. The scattered laser light and fluorescent light are collected, separated and measured.

The cytometer has seven sensors, each generating a voltage pulse signal as each cell passes through the laser beam. The voltage pulse signal is proportional to the intensity of the light the sensor received. The cytometer electronics amplify, condition, integrate and analyze these pulses.

The results of sample analysis appear on the workstation screen as graphs in which the user defines the parameters on the plot axes. To analyze the data, regions and gates are defined by the user to select the cells of interest, and then statistics are generated.

5.0 Indications for Use:

The FC 500 MPL is a system for the qualitative and quantitative measurement of biological and physical properties of cells and other particles. These properties are measured when the cells pass through one or two laser beams in single-file.

6.0 Description of the modification:

The FC 500 MPL design is based upon the FC 500 flow cytometer. Hardware, software and labeling changes were made to support sample presentation / introduction from multi-well plates. Additional software and labeling modifications were made to support a 21 CFR Part 11 compliance option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
C/O Lourdes Coba
11800 SW 147th Avenue
Miami, Florida 33196-2500

Re: k071681
Trade/Device Name: FC 500 MPL Flow Cytometer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 18, 2007
Received: June 19, 2007

OCT 4 2007

Dear Ms. Coba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K071681

Device Name: **FC 500 MPL Flow Cytometer**

Indications for Use:

The Cytomics FC 500 MPL is a system for the qualitative and quantitative measurement of biological and physical properties of cells and other particles. These properties are measured when the cells pass through one or two laser beams in single-file.

Prescription Use ____X___ (per 21 CFR 801 Subpart D) OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071681